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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,308	03/30/2004	Luca Battistini	725.1048-PCT-CIP-CON	1799

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EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
02/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@lmiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/812,308	BATTISTINI ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/30/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In view of the appeal brief filed on 19 October 2009, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

2. To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

3. A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

Response to Applicants' Arguments

4. Applicants arguments filed 06/30/2009regarding the rejection of claims 9-11 made by the Examiner under 35 USC 103(a) over Mistrello et al. (Immunopharmacology, 1985) in view of Hashimoto et al. (GB 2246350A) o ralternatively Lenardo (WO 94/28926) have been fully considered and they are found persuasive. This rejection has been withdrawn as Mistrello teaches that the claimed compound is not useful for treating arthritis which was argued by the previous

Examiner to be equivalent with uveitis. However, there is no link between rheumatoid arthritis and uveitis, and thus one would not expect the claimed method upon the references combination.

New Rejections

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 9–11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mistrello et al. (Immunopharmacology, 1985; of record) in view of Nitecki et al. (US 4895872; published 01/23/1990), Chen et al. (US 5273979; published 12/28/1993) and Sharpe et al (US 5484788; published 01/16/1996).**

9. Mistrello teaches DL111-IT (= ST1959 = Applicants claimed compound) is a useful immunosuppressive agent effective in inhibiting the antibody response to both thymus-dependent (SRBC) and thymus-independent (LPS) antigen (page 168, see discussion section, especially col. 1, first full para). Mistrello teaches various methods of treating autoimmune disorders including suppressing antibody response to various antigens and skin grafts. The effect on antibody response was significant. Suppression of antibody response showed dose dependency, and after antigen (SRBC) insult control mice exhibited antibody counts of 115 IgG and IgM/spleen whereas those treated with 5 mg/kg of DL111-IT displayed only 7 115 IgG and IgM/spleen (see Table 1). For skin grafts, administration of DL111-IT greatly. This was achieved by the compounds ability to suppress autoantibodies associated with graft disease (see Table V).

10. Mistrello do not teach treating uveitis with DL111-IT.

11. Nitecki is directed to immunosuppressive analogues and derivatives of succinylacetone. It's stated that immunosuppressive drugs are used to treat autoimmune disease much as they are used to treat organ tissue transplants and graft versus host disease. An exemplified autoimmune disease includes uveitis (see column 2, lines 35-45).

12. Chen is directed to cyclic hemiacetal immunosuppressant agents. It's taught that the compounds are immunosuppressive and are useful for treating graft versus host disease as well as autoimmune disease such as uveitis (see column 10, lines 10-15).

13. Sharpe is directed to spiperone derivatives as immunosuppressive agents. It's taught that these derivatives are capable of suppressing the immune system in animals and can be used to treat a myriad of immunological disease such as graft verse host disease and uveitis (see column 13, lines 15-25).

14. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Mistrello and Nitecki, Chen and Sharpe with a reasonable expectation for success in arriving at a method of treating uveitis with DL111-IT. Mistrello shows that DL111-IT is a very effective immunosuppressive capable of reducing antibody product due to antigen insult, wherein the antigen is that of foreign blood cells or skin allografts. While Mistrello fails to teach the immunosuppressant as being useful for treating uveitis, any ordinary person could have been capable of looking to the art only to find that other commonly used immunosuppressant useful for treating graft verse host disease are also useful for treating autoimmune disorders like uveitis. The art is very clear that compounds useful for treating one disease are useful for treating the other. See Nitecki, Chen and Sharpe. Thus, it is the position of the Examiner that any person that knows DL111-IT is useful in the treatment of graft disease, would reasonably expect DL111-IT to also provide immunosuppressive benefit in the treatment of uveitis. Additionally, although Mistrello specifically faisl to teach humans as being potential subjects for which DL111-IT could be administered for immunosuppressant benefit, any person of ordinary skill in the art would readily envisage and endeavor to provide DL111-IT to a human subject. Moreover, the references to Nitecki, Chen and Sharpe each teach that immunosuppressant drugs are useful for treating diseases in humans. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the

invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. **Claims 9-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of US Patent No. 6797722 in view of Chen et al. (US 5273979)**.

16. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims in the instant application and the '722 patent are drawn to a methods of treating an autoimmune diseases (i.e. uveitis) with the chemically same compound. While the patent document is generically directed to treating autoimmune disease, and MS, lupus and rheumatoid arthritis, more specifically., the instant application recites treating uveitis which is well known to be an autoimmune disease, but fails to claim treating the other enumerated

diseases, i.e. lupus, MS, and rheumatoid arthritis. Chen teaches that immunosuppressant drugs are useful for treating various autoimmune diseases such as lupus, uveitis, rheumatoid arthritis and MS. Seecolumn 10, lines 10-15. Thus, one could have taken the agent of the instant application and used it for treating other conditions such as MS and lupus with a reasonable expectation in providing immunosupression and therefore treating the disease. Therefore, the scope of the claims in the cited applications are overlapping and the differences are considered to be obvious over each other.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611

January 25, 2010

/David J Blanchard/
Acting Supervisory Patent Examiner, Art Unit 1611